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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,815	02/06/2004	Lukas Eisermann	31132.40	8264
46333	7590	07/09/2007		
HAYNES AND BOONE, LLP 901 MAIN ST SUITE 3100 DALLAS, TX 75202			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 07/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/773,815

Applicant(s)

EISERMANN ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/17/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22,23,28,30 are rejected under 35 U.S.C. 102(e) as being anticipated by Boehm et al. (2004/39384). Fig. 3 shows a vertebral correction system comprising first and second members **54** and a connecting member **66** between the two members. Boehm et al. disclose the engaging members are screws and are inserted in the vertebrae, paragraph 53. Boehm then discloses the connecting member is coupled to the screws and rotated to move the vertebrae, paragraphs 56,59.

Claims 22,23,28,30 are rejected under 35 U.S.C. 102(a) as being anticipated by Nohara et al. (EP 1222900). Nohara et al. disclose the method of correcting spondylolisthesis between vertebrae by engaging a first spinal member with a first vertebra and engaging a second spinal member with a second vertebra, Fig. 1. It can be seen that first and second screws **5** are inserted into the spinal vertebrae and that a connecting member (**1**) is coupled to the first and second spinal screws. It is inherent that the connecting member is rotated to some degree to align and affix with the two

screws and causes some vertebral movement since these connecting rods and screws are used to correct misaligned vertebrae.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-15, 17, 20-24, 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (6964665) in view of Kapp et al. (4554914). Thomas et al. disclose (Fig. 7c) a spondylolisthesis correction system including bone screws **12** laterally inserted into first and second vertebrae and a connecting member or rod **50** is spanned between the vertebrae. Thomas shows the spondylolisthesis condition and discloses the system is used to correct this condition, col. 6, lines 45-51. However, Thomas et al. fail to disclose that the spinal disc would need to be removed or explicitly preparing offset openings. Kapp et al. teach removing an intervertebral disc to define a space between vertebrae and preparing the space for a "prosthetic joint implant", col. 4, lines 17-20. Kapp also teaches (fig. 1) that the slots or bores **44** formed for the insertion members **40** are offset. It would have been obvious to one of ordinary skill in the art to remove disc material if necessary or diseased as taught by Kapp et al. when performing the procedure of Thomas et al. and inserting bone screws and a connecting member such that no further damage or painful conditions continue and the degenerative area is stabilized. With respect to claim 21, it would have been an obvious expedient to use a

rotatable wrench to rotate the connecting member as such only involves routine skill in the art and would give the surgeon good torque to move the rod.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. '665 in view of Kapp et al. '914. as applied to claim 17 above, and further in view of Wagner et al. (6030389). Thomas et al. as modified by Kapp et al. is explained supra. However, Thomas in view of Kapp fail to disclose the type of screws used in the surgical procedures. Wagner et al. teach that there are two types of screws used in spinal stabilization procedures, bi-cortical and uni-cortical and enable the surgeon to decide which to use based on the type of device the screws are used with, col. 1, lines 31-44. It would have been obvious to one of ordinary skill in the art to utilize either bi-cortical or uni-cortical as taught by Wagner et al. in the method of spinal repair with the device of Thomas et al. as modified by Kapp such that the implantable screws and connectors remain in place and provide the proper alignment for the patient.

Claims 14-16,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. '665 in view of Kapp et al. '914. as applied to claim 13 and 24 above, and further in view of Marnay (5314477). Thomas et al. as modified by Kapp et al. is explained supra. However, Thomas in view of Kapp fail to disclose the laterally forming slots in the vertebrae for laterally extending keels or that the spacer inserted between the vertebrae permits articulation. Kapp also teaches (Fig. 2) the prosthetic implant having at least one offset projection from another {since there are two projections (60, 66) each inserted in the first and second vertebrae}, but does not teach the projections as keels. Marnay teaches to form lateral slots in the vertebrae, col. 3, lines 7-

13,17,18,48-50, col. 7, lines 37,52,53. Marnay also shows (Fig. 2) laterally-extending keels to fit in the slots prepared in the vertebrae. Marnay also illustrates (Fig. 1) a spinal spacer that permits articulation. It would have been obvious to one of ordinary skill in the art to use the teaching of Marnay to prepare slots for laterally-extending keels on a limited articulating implant and modify the device of Thomas et al. in view of Kapp et al. such that the vertebral engaging members that are part of the joint replacement device has a larger attachment surface area by using keels which would better stabilize the implant between the vertebrae and allow some mobility between the vertebrae.

Response to Arguments

Applicant's arguments filed 4/17/07 have been fully considered but they are not persuasive. Applicant argues that the Nohara system does not adjust the positions of the vertebrae. However, the Examiner is not convinced since these systems are used to correct for deformities, misalignment and injuries. They would not be used to just hold two vertebrae together in an axial position since they are positioned adjacent one another vertically because the human spine is designed to be held together in an axial or vertical direction. Thus, when fixation rods are used they are intended to hold the vertebrae in adjusted positions after re-aligning or the surgeon has accomplished correction procedures. Inherently, some rotation about the screw takes place to move the rod and affix with the second screw.

Applicant's arguments with respect to claim 12 and 22 also have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

Brian Pellegrino
BRIAN E. PELLEGRINO
PRIMARY EXAMINER